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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new non-provisional applications under 37 CFR 1.53(b))

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First Inventor or Application Identifier:		MARK CHRISTOPHER ALBRECHT			
Title:		EVALUATION OF BURST TEST RESULTS			
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Application Elements (See MPEP chapter 600 concerning utility patent application contents)			ADDRESS TO: Assistant Commissioner For Patents BOX PATENT APPLICATION Washington, D.C. 20231		
1. <input checked="" type="checkbox"/> Fee Transmittal Form (Submit an original, & duplicate for fee processing) 2. <input checked="" type="checkbox"/> Applicant claims small entity status 3. <input checked="" type="checkbox"/> Specification [Total Pages <u>28</u>] (preferred arrangement set forth below) <ul style="list-style-type: none"> • Descriptive title of the Invention • Cross References to Related Applications • Statement Regarding Fed sponsored R&D • Background of the Invention • Brief Summary of the Invention • Brief Description of the Drawings (if filed) • Detailed Description • Claim(s) • Abstract of the Disclosure 4. <input checked="" type="checkbox"/> Drawing(s) (35 USC 113) [Total sheets <u>13</u>] 5. <input checked="" type="checkbox"/> Oath or Declaration [Total Pages <u>3</u>] a. <input checked="" type="checkbox"/> Newly executed (original or copy) b. <input type="checkbox"/> Copy from prior application (37 CFR 1.63(d)) (for continuation/divisional with Box 17 completed) i. <input type="checkbox"/> Deletion of Inventor(s) Signed statement attached in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b) 6. <input type="checkbox"/> Application Data Sheet. See 37 CFR 1.76			7. <input type="checkbox"/> CD-ROM or CD-R in duplicate, large table, or Computer Program (Appendix) 8. <input type="checkbox"/> Nucleotide and/or Amino Acid Sequence Submission (if applicable, all necessary) a. <input type="checkbox"/> Computer Readable Form (CRF) b. <input type="checkbox"/> Specification Sequence Listing on: i. <input type="checkbox"/> CD-ROM or CD-R (2 copies); or ii. <input type="checkbox"/> paper c. <input type="checkbox"/> Statement verifying identity of above copies ACCOMPANYING APPLICATION PARTS 9. <input type="checkbox"/> Assignment Papers (cover sheet & document(s)) 10. <input type="checkbox"/> 37 CFR 3.73(b) Statement [Power Of Attorney] (when there is an assignee) 11. <input type="checkbox"/> English Translation Document (if applicable) 12. <input type="checkbox"/> Information Disclosure Statement (IDS/PTO1449) [Copies of IDS Citations] 13. <input type="checkbox"/> Preliminary Amendment (___ pgs.) 14. <input checked="" type="checkbox"/> Return Receipt Postcard (CPEP 503) (Should be specifically itemized) 15. <input type="checkbox"/> Certified Copy of Priority Document(s) (if foreign priority is claimed) 16. <input checked="" type="checkbox"/> Express Mail Certification 17. <input checked="" type="checkbox"/> OTHER: Check # _____ (\$695)		
17. If a CONTINUING APPLICATION, check appropriate box and supply the requisite information: <input type="checkbox"/> Continuation <input type="checkbox"/> Divisional <input type="checkbox"/> Continuation-In-Part of prior application no.: ____ / ____ Prior application information: Examiner: _____ Group/Art Unit: _____					
18. CORRESPONDENCE ADDRESS					
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FEE TRANSMITTAL

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First Named Inventor:	MARK CHRISTOPHER ALBRECHT
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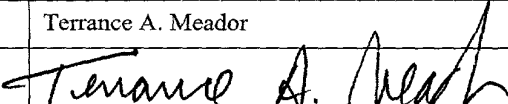
2. UTILITY Basic Filing Fee & Claims

(1) For	(2) No. filed	(3) No. extra	(4) Large Entity	(5) Small Entity	(6) Calculations
Basic Filing Fee	XX	XX	\$ 710.00	\$355.00	\$ 355.00
Total Claims	40 - 20 =	20	X \$ 18.00	X \$ 9.00	\$ 180.00
Independent Claims	7 - 3 =	4	X \$ 80.00	X \$ 40.00	\$ 160.00
Multiple Dependent Claim(s) (if applicable)			\$ 260.00	\$130.00	\$ 000.00
Total of above Calculations =					\$ 695.00

Basic Filing Fee	Large Entity	Small Entity	Total
Design filing fee	\$ 320.00	\$ 160.00	\$ 000.00
Reissue filing fee	\$ 710.00	\$ 355.00	\$ 0.00
Provisional filing fee	\$ 150.00	\$ 75.00	\$ 0.00
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3. ADDITIONAL FEES

Fee Description	Large Entity	Small Entity	Other
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Name (print/type)	Terrance A. Meador	Registration No.: (Attorney/Agent)	30,298
Signature		Date	26 October 2000

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 SIGNATURE

EVALUATION OF BURST TEST RESULTS

BACKGROUND

5 1. Field of the Invention

The invention relates generally to testing of packaging seals. More specifically, the invention relates to evaluation of seal testing results.

10 2. Background of the Invention

The packaging of sterile products such as medical devices must be manufactured according to strict specifications in order to prevent contamination of the product. The packaging for these products often includes one or more seals where portions of the packaging are bonded. A variety of specifications and regulations are directed toward the integrity of these seals. As a result, the manufacturers and users of this packaging often must have access to technology for testing these seals.

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There are a variety of methods and devices available for testing packaging seals. The two most common are peel testing and burst testing. Peel testing is performed by cutting the package into a several pieces that each have a portion of the seal. The seal on each piece is pulled apart at a constant velocity while measuring the force on the seal. Peel testing is known to provide reliable seal integrity results. However, because the packaging must be cut into several pieces that are each tested independently, evaluating the integrity of the seal on a single packaging can take a long time. Additionally, the testing can miss the weakest part of the seal.

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Burst testing includes inflating the packaging with a fluid until the seal bursts. The most common methods involve recording the maximum pressure reached before the package seal ruptures. Although burst testing has proven to be a quicker test, the results are often unreliable. Additionally, there is currently not a reliable method

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available for comparing burst test results with peel test results. For the above reasons, there is a need for a reliable burst test and a need for a method of processing the results so they can be compared with peel test results.

5 SUMMARY OF THE INVENTION

The invention relates to a method for evaluating a seal on a package. The method includes determining the value of a burst test force parameter. The burst test force parameter being a parameter that results from a force placed on the package during a burst test. The method also includes using the value of the burst test force parameter to determine a value of a peel test force parameter for the package. The peel test force parameter being a parameter that results from a force placed on the package during a peel test.

Another embodiment of the method includes using the value of the burst test force parameter to determine a seal integrity. The seal integrity is a value that is determined using a peel test under specific parameters to evaluate the quality of the seal. Because the peel test seal integrity is determined using a peel test, the method allows burst test results to be converted to a seal integrity value that can be compared with the seal integrity values that are generated directly from peel tests. Hence, an embodiment of the method allows for comparison of burst test results and peel test results.

The invention also relates to data for use with a seal testing device. The data includes burst test force parameter values related to peel test force parameter values. The relation indicates the burst test force parameter value and the peel test force parameter value that would result from performing a burst test and a peel test such that a seal would peel at substantially the same velocity during the burst test and during the peel test.

The invention also relates to a database for use with a seal testing device. The database includes a plurality of burst test force parameter values and a plurality of peel test force parameter values. Each peel test force parameter value is associated with one of the burst test force parameter values. Additionally, an associated peel test force parameter value and burst test force parameter value result from a burst test and peel test performed such that a seal would peel at substantially the same velocity during the burst test and during the peel test.

Another embodiment of a database for use with a seal testing device includes a plurality of seal velocity values and a plurality of peel test force parameter values. Each peel test force parameter value is associated with one of the seal velocity values and results from performing a peel test at the associated peel velocity. In one embodiment of the invention, a plurality of these databases are each associated with a seal integrity. The plurality of databases can be arranged in a three dimensional database.

The invention also relates to a method of preparing data for use with a seal testing device. The method includes performing a burst test and a peel test such that a type of seal on a type of package peels at substantially the same velocity during the peel test and the burst test. The method also includes evaluating a burst test force parameter value that results from a force applied to the package during the burst test and evaluating a peel test force parameter value that results from a force applied to the package during the peel test. The method further includes storing the value of the burst test force parameter such that it is associated with the value of the peel test force parameter.

Another method of preparing data for use with a seal testing device includes performing a plurality of peel tests on packages that each have the same seal integrity rating. Each peel test is performed at a different peel velocity. The method also includes evaluating a peel test force parameter value resulting from each peel test. The method further includes storing the peel test force parameter values such that the

peel test force parameter value for a particular peel test is associated the with the peel velocity at which the particular peel test was performed. In one embodiment of the invention, this method is repeated for packages having different seal integrities. This embodiment can further include storing the peel test force parameters and the
5 associated peel velocities such that the peel test force parameters and the associated peel velocities are associated with a seal integrity.

BRIEF DESCRIPTION OF THE DRAWINGS

- 10 Figure 1 illustrates a system for evaluating seal test results.
Figure 2A is a top view of a package having a seal.
Figure 2B is a cross sectional view of the package shown in Figure 2A taken along the line labeled A.
Figure 2C illustrates a seal being peeled during a peel test.
15 Figure 2D illustrates the seal being peeled apart during a burst test
Figure 3 illustrates a pressure profile during a constant pressure burst test.
Figure 4 illustrates a test conversion database.
Figure 5 illustrates a test conversion relationship expressed as a mathematical expression.
20 Figure 6 illustrates test conversion relationships for different package types.
Figure 7A illustrates an integrity evaluation database.
Figure 7B illustrates a plurality of two dimensional integrity evaluation databases that are each associated with a seal integrity arranged in a three dimensional integrity evaluation database.
25 Figure 8 illustrates peel test force parameter values plotted against peel velocity values for seals of a particular integrity.
Figure 9 is a graphical representation of integrity evaluation data.
Figure 10 illustrates a method of evaluating the results of a burst test.

Figure 11 illustrates a method of generating data for a test conversion database.

Figure 12 illustrates a method of generating integrity evaluation data.

5 **DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT**

The invention relates to a system for evaluating seals on a package. A burst test is performed on the package such that the seal peels apart. The burst test can be either a restrained burst test or an unrestrained burst test and is performed such that a substantially constant pressure is maintained while the seal is peeling. The burst test is used to evaluate several parameters. Suitable parameters include, the velocity at which the seal peels and the value of one or more burst test force parameters. Burst test force parameters are parameters that result from a force being applied to the seal during the burst test. Accordingly, the value of a burst test force parameters provides information about the force applied to the seal during the burst test. For example, the average pressure within the package over the period of time required for the seal to completely peel can be evaluated.

In one embodiment of the invention, the value of a burst test force parameter is converted to a peel test force parameter value. A peel test force parameter is a parameter that result from a force being applied to the seal during a peel test. Accordingly, the value of a peel test force parameters provides information about the force applied to a seal during a peel test. For example, the average force applied to a seal over the period of time required for the seal to completely peel can be evaluated.

The burst test force parameter value is converted to a peel test force parameter value by comparing the burst test force parameter value with a test conversion relationship. A test conversion relationship associates burst test force parameter values with peel test force parameter values. The association indicates the burst test force parameter value and the peel test force parameter value that would result from

performing a burst test and a peel test such that a seal would peel at substantially the same velocity during the burst test and during the peel test. Accordingly, a burst test force parameter value for a particular seal can be compared to the relationship to determine a peel test force parameter value for the seal. The resulting peel test force parameter value is the approximate value of the peel test force parameter that would result if a peel test had been performed on the seal at the peel velocity that occurred during the burst test. Hence, the resulting peel test force parameter value can be directly compared with peel test force parameter values generated from peel tests.

A method for generating a test conversion relationship includes performing a constant pressure burst test on a package. The value of a burst test force parameter and a peel velocity are evaluated. A peel test is then performed on either an undisturbed segment of the package or on a seal that was manufactured to have a seal quality that is substantially the same as the seal of the burst package. The peel test is performed at the peel velocity that resulted during the burst test. A peel test force parameter value is evaluated during the peel test. The burst test force parameter value and the peel test force parameter value are then stored such that the burst test force parameter value is associated with the peel test force parameter value. For instance, the burst test force parameter value and the peel test force parameter value can be stored in a database that associates the burst test force parameter value with the peel test force parameter value. Because the burst test force parameter value and the associated peel test force parameter value are generated from tests performed such that the seal peeled at approximately the same peel velocity, the peel test force parameter value can be approximately determined for a package by performing a constant pressure burst test on the package and comparing the results of the burst test to the database associating burst test force parameter values with peel test force parameter values.

The system can also employ seal integrity evaluation data. A peel test force parameter value generated as described above can be compared with the seal integrity

evaluation data in order to approximate the seal integrity for a package. As will be described in more detail below, the seal integrity evaluation data can be generated using peel tests. Accordingly, the approximated seal integrity can be directly compared with other integrity values resulting from peel tests. Hence, an
5 embodiment of the invention allows burst test results to be converted to an integrity value that can be directly compared with integrity values generated from peel tests.

Figure 1 illustrates a system 10 for evaluating seal test results. The system 10 includes a seal testing device 12. Suitable seal testing devices include, but are not limited to, a peel testing device and a burst testing device. The system 10 also
10 includes a processing unit 14 in communication with the seal testing device 12, a display 16 and one or more user interfaces 18. The processing unit 14 houses electronics 20 for controlling various operations of the system 10. For instance, the electronics 20 can measure one or more parameters during the testing of a package 20 by the seal testing device 12 and provide additional processing of these parameters
15 according to the methods of the present invention. The display 16 can be used to show parameters that have been measured by the system 10.

An operator can use the one or more user interfaces 18 to interact with the system 10. For instance, the user can change what is shown on the display 16 or vary system 10 settings such as the peel velocity of a peel test or the pressure of a constant
20 pressure burst test. A suitable user interface 18 includes, but is not limited to, a keyboard and a mouse. Although a single processing unit 14, user interfaces 18 and display 16 are illustrated, the system 10 can include a plurality of processing units 14, displays 16 and user interfaces 18. Additionally, the system 10 can include more than one seal testing device 12. For instance, the processing unit 14 can be in
25 communication with both a seal testing device 12 and a burst testing device. The processing unit 14 can then store and process data achieved by testing on either device.

The electronics 20 can include one or more processors for performing instructions stored or carried on a machine readable medium. Suitable processors include, but are not limited to, programmed general purpose digital computers, microprocessors, digital signal processors (DSP), integrated circuits, application specific integrated circuits (ASICs), logic gate arrays and switching arrays.

Suitable machine readable media include, but are not limited to, RAM, disk drives, optical discs such as a compact disk (CD), CD-ROM, CD-R (a recordable CD-ROM that can be read on a CD-ROM drive), CD-RW (multiple-write CD), CD-E (recordable and erasable CD), or DVD (digital video disc). Alternatively, instead of, or in addition to an optical disc, the machine readable media can include one or more of the following: a magnetic data storage diskette (floppy disk), a Zip disk, DASD storage (e.g., a conventional "hard drive" or a RAID array), magnetic tape, RAM, electronic read-only memory (e.g., ROM, EPROM, or EEPROM), paper punch cards, or transmission media such as digital and/or analog communication links. In some instances, one or more of the machine readable media are positioned outside or remote from the processing unit 14. For instance, the machine readable medium may be part of, or may be connected to, a server computer that is connected to a network, in order to make the machine-readable code available to other computers.

Figures 2A-2D illustrates a package 20 having a seal 28. Figure 2A is a top view of the package 20 while Figure 2B is a cross sectional view of the package 20 taken along the line labeled A in Figure 2A. The package 20 includes two pieces of material bonded together at a seal 28. The seal 28 is illustrated as a darkened area to show the bonded nature of the material. The seal length is labeled L and the seal width is labeled W.

Figure 2C illustrates a seal 28 being peeled during a peel test. The materials are pulled in opposite directions as illustrated by the arrow labeled A. The force on the seal 28 causes the seal 28 to peel apart. The seal 28 is typically pulled apart at a constant velocity and a peel test force parameter measured as the seal 28 is peeled. A

peel test force parameter is a parameter that result from a force being applied to the seal 28 during a peel test. Accordingly, the value of a peel test force parameters provides information about the force applied to a seal 28 during a peel test. Suitable peel test force parameters include, but are not limited to, force, work and power. The peel test force parameter can also be an average value such as average force during the peel of the seal 28. The peel test force parameter can also be measured in terms of length such as force per unit length or work per unit length. Additionally, the peel test force parameter can be broken down into directional components such as vertical force and/or horizontal force applied to the seal 28. The peel test force parameter can also be directed toward a feature such as a peak force or a minimum force during the peel. One peel test force parameter can be measured during the peel test and converted into another peel test force parameter after the peel test. For instance, the force can be measured as the seal 28 is peeled. The measured force can be integrated over time in order to determine an average force during the peel test. Combinations of these peel test force values can also be used.

Figure 2D illustrates the seal 28 being peeled apart during a burst test. The seal 28 is pulled apart by the pressure within the package 20. As a result, the force on the seal 28 is not necessarily in opposing directions as it is during the peel test.

As described above, the burst test can be a performed at constant pressure. A constant pressure burst test can be accomplished with software, mechanics or combinations of both. For instance, the processing unit 14 can monitor a pressure measuring device and control the introduction of the fluid into the package 20 until a target pressure is achieved with the package 20. The processing unit 14 can control additional introductions of fluid into the package 20 to maintain the pressure at the target pressure. Alternatively, the burst testing device can include a pressure regulator that acts as a release valve when the pressure in the package 20 exceeds the target pressure. The fluid can be introduced into the package 20 at a constant rate

because the pressure regulator prevents the pressure from exceeding the target pressure.

Figure 3 illustrates a typical profile of pressure versus time for a constant pressure burst test. A fluid is introduced into the package 20 at a rate that causes the pressure in the package 20 to quickly rise to the target pressure. The target pressure is above a pressure that causes the seal 28 to peel. The seal 28 begins to peel at the time labeled t_0 . Shortly after the seal 28 begins to peel, the pressure within the package 20 reaches the target pressure. The seal 28 bursts at the time labeled t_f . The pressure drops off rapidly once the seal 28 peels far enough for the fluid to rapidly escape from the package 20.

Because the target pressure within the package 20 is above the pressure where the seal 28 begins to peel, the seal 28 begins to peel before the target pressure can be achieved. As a result, a portion of a constant pressure burst test is presumably performed with a dynamic pressure.

The constant pressure burst test is used to evaluate several parameters. A parameter that can be measured during the constant pressure burst test is the velocity at which the seal 28 peels. Applying the principles of conservation of work to a burst test and presuming a very small internal area change or that restraining plates maintain a substantially constant ratio of exposed area (area not in contact with the plates) to seal perimeter shows that when a package 20 is burst at constant pressure, the velocity that the seal 28 peels remains constant. Accordingly, the peel velocity of a seal 28 peeled under constant pressure can be determined by dividing the width of the seal 28 by the time required for the seal 28 to peel. The time for the seal 28 to peel is illustrated in Figure 3 as the time from t_0 to t_f . This time is called the peel time below.

The processing unit 14 can measure the peel time. The value of the pressure where t_0 occurs can be approximated from theoretical equations that are entered into the processing unit 14. The processing unit 14 can then use these equations to find

the pressure where t_0 occurs and start measuring time once the pressure is reached. Alternatively, t_0 can be experimentally determined by slowly raising the pressure in the package 20 to determine the pressure where the seal 28 begins to peel. A user interface can be used to enter this pressure into the processing unit 14. The

5 processing unit 14 can start measuring time once the entered pressure is reached. The processing unit 14 stops measuring time upon identifying the sudden pressure drop that occurs at t_r .

In some embodiments, the processing unit 14 can automatically measure the seal width. For instance, the processing unit 14 can be in communication with a

10 camera based vision system. Camera based vision systems use high resolution/high velocity video or digital cameras to take pictures of an object. Software is then used to create measurements based on a known ratio of pixels to unit of measure. These type of systems range from simple "pixel counters" that count light vs. dark pixels to systems that use more complicated algorithms to "see" fine contrast levels, faint lines,

15 and other difficult to detect features. Lighting also plays a very important role in these systems. Color of light, polarization, filters on the cameras, etc. can all be used to enhance the seal 28 for easier observation. Alternatively, the seal width can be manually measured with an instrument such as calipers. A user interface can then be used to enter the measured seal width into the processing unit 14. The processing unit

20 14 can determine the average velocity that the seal 28 peels during the burst test by dividing the seal width by the peel time.

Other parameters that can be determined from the burst test include, but are not limited to, the value of one or more burst test force parameters. Burst test force parameters are parameters that result from a force being applied to the seal 28 during

25 the burst test. Accordingly, the value of a burst test force parameters provides information about the force applied to the seal 28 during the burst test. Suitable burst test force parameters include, but are not limited to, pressure, force, work and power. The burst test force parameter can also be an average value such as average pressure

during the peel of the seal 28. The burst test force parameter can also be measured in terms of length such as work per unit length. Additionally, the burst test force parameter can be broken down into directional components such as vertical force and/or horizontal force applied to the seal 28. The peel test force parameter can also be directed toward a feature such as a peak pressure and/or a minimum pressure during the peel. One burst test force parameter can be measured during the peel test and converted into another peel test force parameter after the peel test. For instance, the pressure can be measured as the seal 28 is peeled. The measured force can then be integrated over time in order to determine an average pressure. Indirect indicators of the force applied to the seal 28 during the burst test can also be employed as the burst test force parameter. For instance, the flowrate of fluid into and/or out of the package during the burst test can be used as the burst test flow rate. Combinations of the burst test force values listed above can also be used.

One burst test force parameter can be measured during the burst test and converted into another burst test force parameter after the burst test. For instance, the processing unit 14 can monitor the pressure within the package 20 during the peel time. The processing unit 14 can apply Equation 1 to determine the average pressure within the package 20 during the peel time. Equation 1 can be easily adapted to measure a time average of other burst test force parameters. These burst test force parameter values can be monitored during the burst test and average values can be determined. Alternatively, one or more burst test force parameter values can be measured during a burst test and then converted to another burst test force parameter value for the purpose of determining an average.

A burst test force parameter can be compared to a test conversion relationship to convert results for a burst test to results for a peel test. The test conversion relationship can be expressed in a test conversion database 30 such as the database illustrated in Figure 4. The test conversion database 30 includes burst test force parameter value fields 32 which are each associated with a peel test force parameter

value field 35. Each burst test force parameter value field 32 lists a burst test force parameter value and each peel test force parameter value field 32 lists a peel test force parameter value. Each peel test force parameter value indicates the peel test force parameter value that would result from a peel test performed at the peel velocity that resulted from performing a burst test at the associated burst test force. The test conversion database 30 can be used to convert a burst test force parameter value to a peel test force parameter value. This conversion can be done by comparing a burst test force parameter value to the test conversion database 30 to find a peel test force parameter value associated with the burst test force parameter value. Interpolation and extrapolation can be employed when the experimental value for the burst test force parameter value is not listed in the test conversion database 30.

The test conversion relationship can also be expressed as a mathematical expression. For instance, a curve fit can be applied to the burst test force parameter value data versus the peel test force parameter value data. The resulting curve can serve as the test conversion relationship. For instance, Figure 5 illustrates burst test force parameter values plotted against peel test force parameter values 32. Specifically, the average pressure measured during a burst test is plotted versus the average force measured during a peel test. A curve is fit to the data. The curve fit can be a continuous curve such as a linear curve fit or a discontinuous curve fit such as a step-wise function. The expression(s) that define the curve can serve as the test conversion relationship. The expression(s) for the curve illustrated in Figure 5 would express the burst test force parameter value as a function of the peel test force parameter value. A burst test force parameter value can be converted to a peel test force parameter value by substituting the burst test force parameter value into the relationship.

The test conversion relationship can be experimentally generated. For instance, the test conversion relationship can be generated by performing a burst test at a constant pressure. A burst test force parameter value is determined along with the

velocity that the seal 28 peels. A peel test is then performed at the determined peel velocity for seal 28 on either an undisturbed segment of the package or on a seal that was manufactured to have a seal quality that is substantially the same as the seal of the burst package. A peel test force parameter value is measured during the peel test.

- 5 The burst test force parameter value and the peel test force parameter value are stored such that the burst test force parameter value is associated with the peel test force parameter value. For instance, the burst test force parameter value and the peel test force parameter value can be entered into a test conversion database 30 such as the database illustrated in Figure 4. Additional data is generated by repeating the above
- 10 steps beginning with performing additional burst tests at different constant pressures.

- The test conversion relationship is generated for each type of package 20. Different package 20 types can include packages of different sizes and shapes. Figure 6 illustrates test conversion relationships for different package 20 types. In particular, the average pressure during a burst test is plotted against the average force during a
- 15 peel test. Because, a test conversion relationship is determined for each type of package 20, each test conversion relationship is associated with a package 20 type. When each test conversion relationship is expressed as a two dimensional database, the two dimensional databases can be arranged in a three dimensional test conversion database consisting of a plurality of two dimensional test conversion databases that
- 20 are each associated with a different package type.

- The peel test force parameter values 32 determined from the test conversion relationship can be compare with integrity evaluation data. The integrity evaluation data can include one or more integrity evaluation relationships that can be used in determining the integrity of a seal 28. An integrity evaluation relationship provides
- 25 the relationship between the peel velocity and the peel test force parameter value for seals of a particular seal integrity.

The integrity evaluation relationship can be expressed as an integrity evaluation database such as the database illustrated in Figure 7A. The integrity

evaluation database includes peel velocity value fields 40 that are each associated with a peel test force parameter value fields. Each test force parameter value field lists a peel test force parameter value that would result from a peel test performed at the peel velocity value listed in the associated peel velocity value field.

5 Because each integrity evaluation relationship is associated with seals of a particular integrity, each integrity evaluation database is associated with seals of a particular integrity. The integrity evaluation databases can be arranged in a three dimensional database as shown in Figure 7B. The three dimensional integrity evaluation database includes a plurality of two dimensional integrity evaluation
10 databases. Each of the two dimensional integrity evaluation databases is also associated with a seal integrity. Each two dimensional integrity evaluation database can include a seal integrity field 43 where the seal integrity associated with the two dimensional integrity evaluation database can be entered.

 The integrity evaluation relationship can also be expressed as a mathematical
15 expression. For instance, a curve fit can be applied to the peel test force parameter value versus the peel velocity data. The expression for the resulting curve can serve as the test conversion relationship. For instance, Figure 8 illustrates peel test force parameter values 32 plotted against peel velocity values for seals of a particular integrity. Specifically, the average force measured during a peel test is plotted versus
20 the average velocity during a peel test. A curve is fit to the data. The curve fit can be continuous such as a linear curve or a discontinuous curve such as a step-wise function. The expression(s) that define the curve can serve as the integrity evaluation relationship. The expression(s) for the curve illustrated in Figure 8 would express the peel test force parameter value as a function of the peel velocity for a seal 28 of a
25 particular integrity.

 Figure 9 is a graphical representation of integrity evaluation data. The peel test force parameter value is plotted against the average peel velocity for each seal

integrity. More specifically, the average peel test force is plotted against the average peel velocity. Each of the curves is associated with a particular seal integrity.

The integrity evaluation data can be used to determine the seal integrity for a particular seal. For instance, a constant pressure burst test is performed on a package.

5 A peel velocity and a burst test force parameter value can be determined. The burst test force parameter value is compared to the test conversion relationship to determine a peel test force parameter value. The determined peel test force and peel velocity are then compared to the integrity evaluation data to approximate the seal integrity for the package 20.

10 Figure 9 illustrates approximation of the seal integrity for the package 20. The peel test force and peel velocity determined from a constant pressure burst test are shown as the point labeled A in Figure 9. The point is positioned between a curve determined for seals of integrity II and a curve determined for seals of integrity III. Interpolation and/or other mathematical techniques can be used to approximate the
15 integrity of a seal 28 at point A. Alternatively, the integrity of a seal 28 at point A can be rounded to the integrity of the curve that is nearest to the point or truncated to the integrity of the curve beneath the point or elevated to the integrity of the curve above the point.

Although Figure 9 is used to illustrate a method for estimating the integrity,
20 the method can be performed without using any graphical representation of data. For instance, the interpolation discussed above can be performed using the integrity evaluation databases without creating the graphical representation.

The integrity evaluation relationships can be experimentally generated. For instance, the integrity evaluation relationships can be generated by performing a
25 series of peel tests on seals of a known integrity. A peel velocity and peel test force parameter value is determined for each peel test. The peel velocity and peel test force parameter value are stored such that the peel test force parameter value is associated with the peel velocity. For instance, the peel test force parameter value and the peel

velocity can be entered into an integrity evaluation database such as the database illustrated in Figure 7A. Additional integrity evaluation databases can be generated by repeating the above steps on seals of a different integrity. The integrity evaluation databases can be arranged in a three dimensional integrity evaluation database with seal integrity providing the third dimension.

Figure 10 illustrates a method of evaluating the results of performing a burst test on a package. The method includes a test conversion stage and an integrity evaluation stage. The test conversion stage includes converting the results of the burst test so they can be compared with the results of a peel test. For instance, the test conversion stage can include converting a burst test force parameter value to a peel test force parameter value. The integrity evaluation stage includes using a result of the test conversion stage to evaluate the integrity of the seal. The integrity evaluation can be measured by a peel test. Accordingly, the results of each stage of the method can be compared with peel test results.

The method illustrated in Figure 10 begins at start block 200. A constant pressure burst test is performed on a package 20 at process block 202. A variety of parameters are evaluated at process block 204. The evaluated parameters are each a function of the seal 28 in that the value of each parameter changes as the seal 28 changes. Suitable parameters include, but are not limited to, peel velocity, seal width and peel time. The evaluated parameters can also include one or more burst test force parameter values such as pressure as a function of time during the peel time, average pressure during the peel time. The parameters can be evaluated before, during or after the burst test. For instance, the seal width can be measured before the burst test is performed while the pressure is evaluated during the burst test.

At least one burst test force parameter value is compared to a test conversion relationship at process block 206 to determine a peel test force parameter value. The peel test force parameter value is a force parameter value that can be directly compared to peel test results. As described above, a suitable burst test force

parameter value is average pressure during the peel time. The average pressure can be compared to a test conversion database 20 to determine an average peel test force that is directly comparable to average force parameter values for peel test performed on the same package.

- 5 The peel test force parameter value generated at process block 206 is compared to integrity evaluation data at process block 208. The comparison provides an integrity for a seal 28 on the package 20 that is comparable to seal 28 integrities measured with a peel test. A suitable method for comparing the peel test force parameter value with the integrity evaluation data is illustrated in Figure 9 and the
- 10 accompanying description. The method ends at end block 210.

Figure 11 illustrates a method of generating data for a test conversion database 30. The method begins at start block 220. A constant pressure burst test is performed on a particular package type having a particular seal 28 type at process block 222.

- A variety of parameters including at least the peel velocity and one or more
- 15 burst test force parameter values are evaluated at process block 224. A suitable burst test force parameter value includes, but is not limited to, the average pressure during the peel. The parameters can be evaluated before, during or after the burst test. For instance, the seal width can be measured before the burst test while the peel time is evaluated during the burst test. The seal width can be divided by the peel time to
- 20 determine the peel velocity.

- A peel test is performed at process block 226. The peel test is performed at the peel velocity evaluated at process block 224 on either an undisturbed segment of the package or on a seal that was manufactured to have a seal quality that is substantially the same as the seal of the burst package. One or more peel test force
- 25 parameter values 32 are evaluated at process block 228. A suitable peel test force parameter value includes, but is not limited to, the average force during the peel. The burst test force parameter values and the peel test force parameter value are stored at process block 230. The burst test force parameter value and the peel test force

parameter value are stored such that the burst test force parameter value is associated with the peel test force parameter value. For instance, the burst test force parameter value and the peel test force parameter value can be stored in a row of the test conversion database 30 illustrated in Figure 4. Storing the data can include storing the data in the machine readable medium. The method terminates at end block 232.

As described above, the method illustrated in Figure 11 includes performing a burst test at a constant pressure. Additional data can be generated for the test conversion database 30 by repeating the method of Figure 11 at different pressures. As described above, each test conversion database 30 is associated with a particular package 20 type. Accordingly, when the method of Figure 11 is performed on packages having the same geometry, the generated data can be stored in the same test conversion database 30.

Figure 12 illustrates a method of generating integrity evaluation data. The method starts at start block 240. A peel test is performed on a seal 28 of a known integrity at process block 242. The peel test is performed at a particular peel velocity. A peel test force parameter value is evaluated at process block 244. The peel test force parameter value can be evaluated before or after the peel test is performed. The peel test force parameter value and the peel velocity are stored at process block 246. The peel test force parameter value and the peel velocity are stored such that the peel test force parameter value is associated with the peel velocity and with the integrity of the seal 28. For instance, the peel test force parameter value and the peel velocity can be stored in the same row of an integrity evaluation database that is associated with the integrity of the tested seal 28 such as the integrity evaluation database of Figure 7A. The method terminates at end block 248.

As described above, the method illustrated in Figure 12 includes performing a peel test at a particular velocity. Additional data for an integrity evaluation database can be generated by repeating the method of Figure 12 at a different velocity. As described above, each integrity evaluation database is associated with a particular seal

Other embodiments, combinations and modifications of this invention will
5 occur readily to those of ordinary skill in the art in view of these teachings.
Therefore, this invention is to be limited only by the following claims, which include
all such embodiments and modifications when viewed in conjunction with the above
specification and accompanying drawings.

What is claimed is:

CLAIMS

1. A method for evaluating a seal on a package, comprising:
determining a value of a burst test force parameter, the burst test force
5 parameter being a parameter that results from a force placed on the package during a
burst test; and
using the value of the burst test force parameter to determine a value of a peel
test force parameter for the package, the peel test force parameter being a parameter
that results from a force placed on the package during a peel test.
10
2. The method of claim 1, wherein using the value of the burst test force
parameter to determine a value of a peel test force parameter includes
comparing the burst test force parameter value to a test conversion
relationship associating burst test force parameter values and peel test force parameter
15 values, the association indicating the burst test force parameter value and the peel test
force parameter value that would result from performing a burst test and a peel test
such that a seal would peel at substantially the same velocity during the burst test and
during the peel test.
- 20 3. The method of claim 2, wherein the relationship is expressed as a database
including a plurality of peel test force parameter values that are each associated with a
burst test force parameter value.
4. The method of claim 2, wherein the relationship is expressed as a
25 mathematical expression.
5. The method of claim 1, wherein the burst test is a constant pressure burst test.

6. The method of claim 1, further comprising:
determining the velocity at which the seal peels during the burst test.
7. The method of claim 1, further comprising:
5 using the value of the burst test force parameter to determine an integrity for
the seal, the integrity being generated from a peel test.
8. The method of claim 1, further comprising:
comparing the determined value of the peel test force parameter to integrity
10 evaluation data.
9. The method of claim 8, wherein the integrity evaluation data includes a
plurality of integrity evaluation relationships that provide a relationship between peel
velocity and the peel test force parameter value, each integrity evaluation relationship
15 being associated with a particular seal integrity.
10. The method of claim 1, further comprising:
determining the velocity at which the seal peels during the burst test; and .
comparing the determined value of the peel test force parameter and the
20 determined peel velocity to integrity evaluation data.
11. The method of claim 1, wherein the burst test force parameter value is selected
from the group consisting of:
pressure, work, force, power and rate of fluid inflow.
25
12. The method of claim 1, wherein the peel test force parameter value is selected
from the group consisting of work, force and power.

13. A method for evaluating a seal on a package, comprising:

evaluating a value of a burst test force parameter, the burst test force parameter being a parameter that results from a force placed on the package during a burst test; and

5 using the value of the burst test force parameter to determine a seal integrity, the seal integrity being an integrity value that is determined by performing peel tests on the seal.

14. The method of claim 13, wherein using the value of the burst test force parameter to determine a peel test seal integrity for the seal includes

10 using the value of the burst test force parameter to determine a value of a peel test force parameter for the package; and

comparing the value of the peel test force parameter to seal integrity evaluation data.

15 15. The method of claim 14, wherein the integrity evaluation data includes a plurality of integrity evaluation relationships that provide a relationship between peel velocity and the peel test force parameter value, each integrity evaluation relationship being associated with a particular seal integrity.

20 16. The method of claim 15, further comprising:

determining the velocity at which the seal peels during the burst test; and comparing the determined peel velocity and the value of the peel test force parameter to one or more of the integrity evaluation relationships.

25 17. The method of claim 13, wherein the burst test includes a constant pressure burst test.

18. The method of claim 13, wherein the burst test force parameter value is selected from the group consisting of:

pressure, work, force, power and rate of fluid inflow.

5 19. Data for use with a seal testing device, comprising:

burst test force parameter values; and

peel test force parameter values related to the burst test force parameter values, the relation indicating the burst test force parameter value and the peel test force parameter value that would result from performing a burst test and a peel test

10 such that a seal would peel at substantially the same velocity during the burst test and during the peel test.

20. The data of claim 19, wherein the relationship is expressed in a database.

15 21. The data of claim 19, wherein the database includes a plurality of burst test force parameter values and a plurality of peel test force parameter values that are each associated with one of the burst test force parameter values, an associated peel test force parameter value and burst test force parameter value resulting from a burst test and peel test performed such that a seal would peel at substantially the same velocity
20 during the burst test and during the peel test.

22. The data of claim 19, wherein the relationship is expressed in a mathematical expression.

25 23. The method of claim 19, wherein the burst test force parameter value is selected from the group consisting of:
pressure, work, force and power.

24. The method of claim 19, wherein the peel test force parameter value is selected from the group consisting of work, force and power.

25. A database for use with a seal testing device, comprising:

5 a plurality of burst test force parameter values; and
a plurality of peel test force parameter values that are each associated with one of the burst test force parameter values.

26. The database of claim 25, wherein an associated peel test force parameter value and burst test force parameter value result from a burst test and peel test performed such that a seal would peel at substantially the same velocity during the burst test and during the peel test.

27. The database of claim 25, wherein the database is associate with a type of package.

28. The method of claim 25, wherein the burst test force parameter value is selected from the group consisting of:
pressure, work, force and power.

29. The method of claim 25, wherein the peel test force parameter value is selected from the group consisting of work, force and power.

30. A method of preparing data for use with a seal testing device, comprising:
25 performing a burst test and a peel test such that a type of seal on a type of package peels at substantially the same velocity during the peel test and the burst test;
evaluating a burst test force parameter value that results from a force applied to the package during the burst test;

evaluating a peel test force parameter value that results from a force applied to the package during the peel test; and

storing the value of the burst test force parameter such that it is associated with the value of the peel test force parameter.

5

31. The method of claim 30, wherein storing the value of the burst test force parameter such that it is associated with the value of the peel test force parameter includes

storing the value of the burst test force parameter and the value of the peel test force parameter in a database.

10

32. The method of claim 31, wherein the database is associated with the seal type and the package type.

15

33. The method of claim 30, wherein storing the value of the burst test force parameter such that it is associated with the value of the peel test force parameter includes

storing the value of the burst test force parameter and the value of the peel test force parameter in a machine readable medium.

20

34. The method of claim 30, wherein the burst test force parameter value is selected from the group consisting of:

pressure, work, force, power and rate of inflow.

25

35. The method of claim 30, wherein the peel test force parameter value is selected from the group consisting of work, force and power.

36. A database for use with a seal testing device, comprising:
a plurality of seal velocity values; and
a plurality of peel test force parameter values that are each associated with one
5 of the seal velocity values, each peel test force parameter value resulting from
performing a peel test at the associated peel velocity.
37. The method of claim 36, wherein the database is associated with a particular
seal integrity.
- 10 38. The method of claim 36, wherein storing the value of the peel test force
parameter such that it is associated with the value of the peel velocity includes
storing the value of the peel test force parameter and the value of the peel
velocity in a database.
- 15 39. The method of claim 36, wherein storing the value of the peel test force
parameter such that it is associated with the value of the peel velocity includes
storing the value of the burst test force parameter and the value of the peel test
force parameter in a machine readable medium.
- 20 40. A method of preparing data for use with a seal testing device, comprising:
performing a plurality of peel tests on packages that each have the same seal
integrity rating, each peel test performed at a different peel velocity;
evaluating a peel test force parameter value resulting from each peel test; and
25 storing the peel test force parameter values such that the peel test force
parameter value for a particular peel test is associated the with the peel velocity at
which the particular peel test was performed.

5

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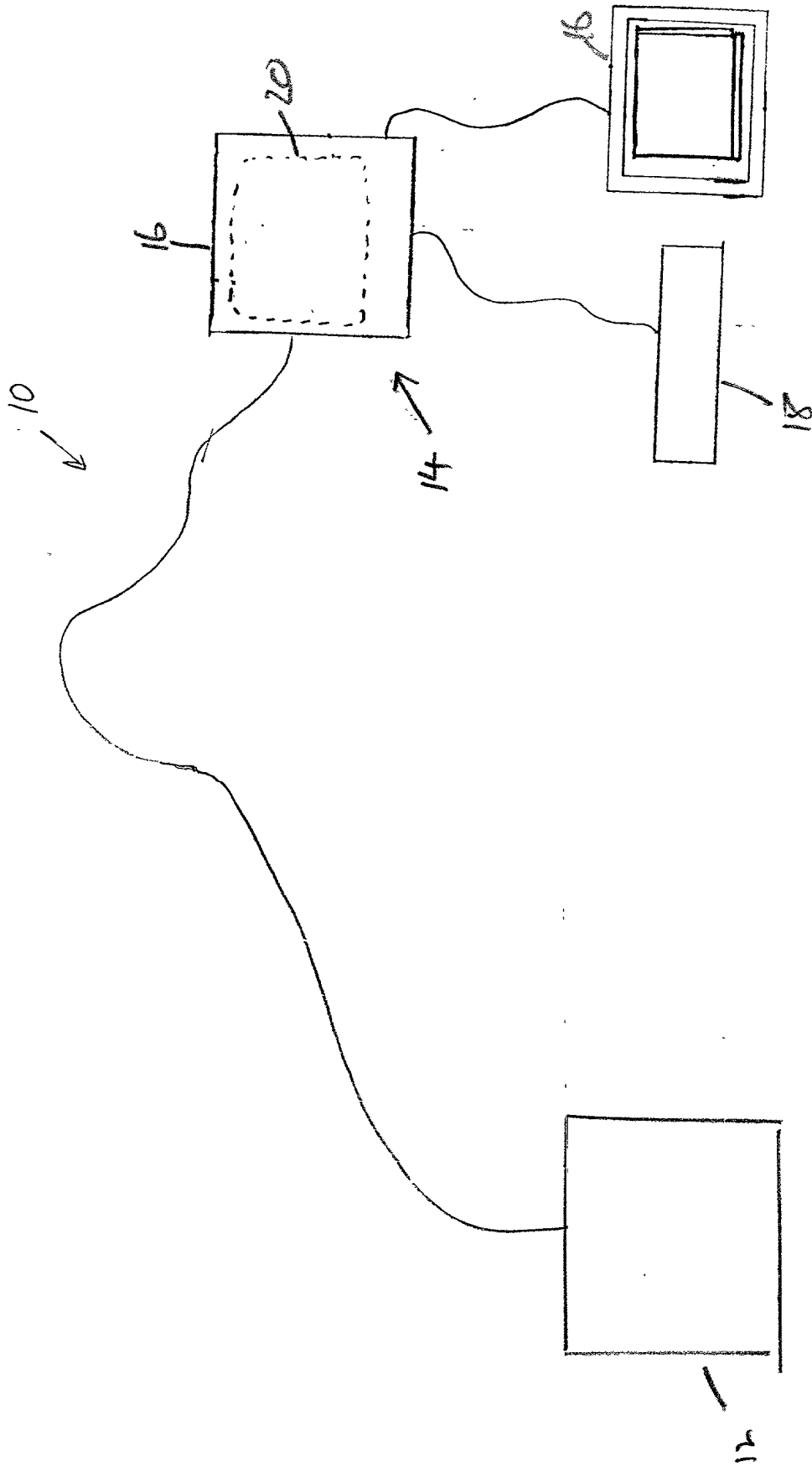


Figure 1

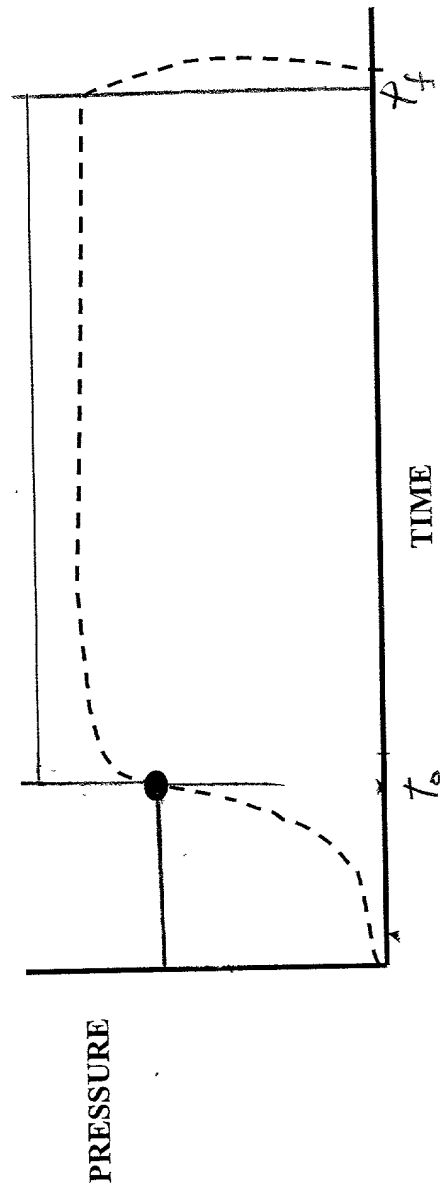
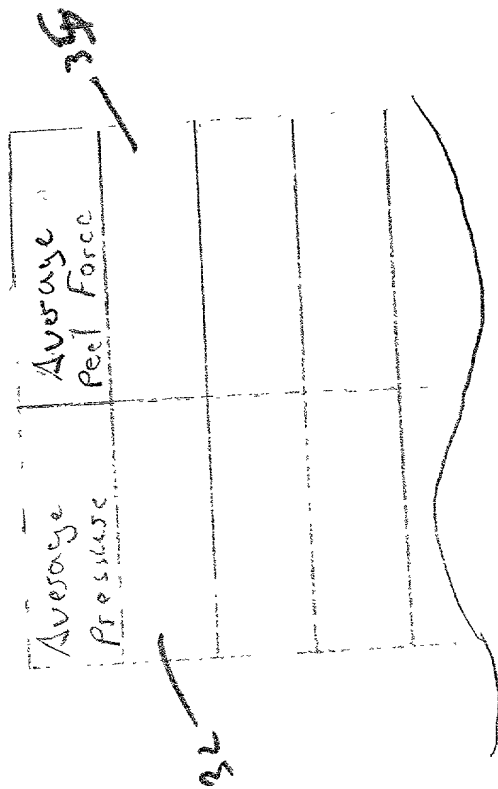


Figure 3

30 ✓



Associated with a
particular package
and seal type

Figure 4

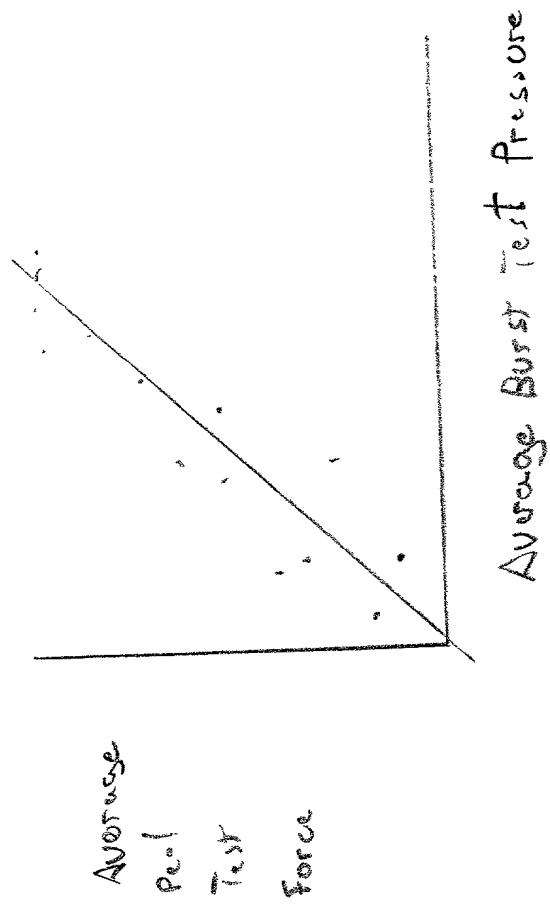


Figure 5

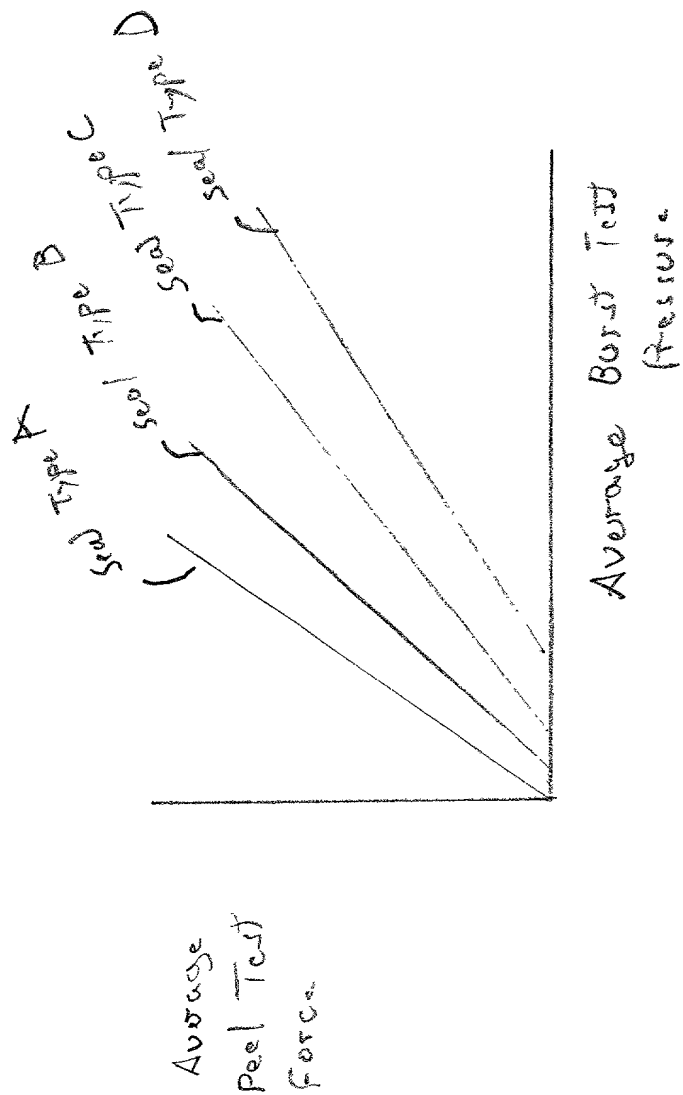


Figure 6

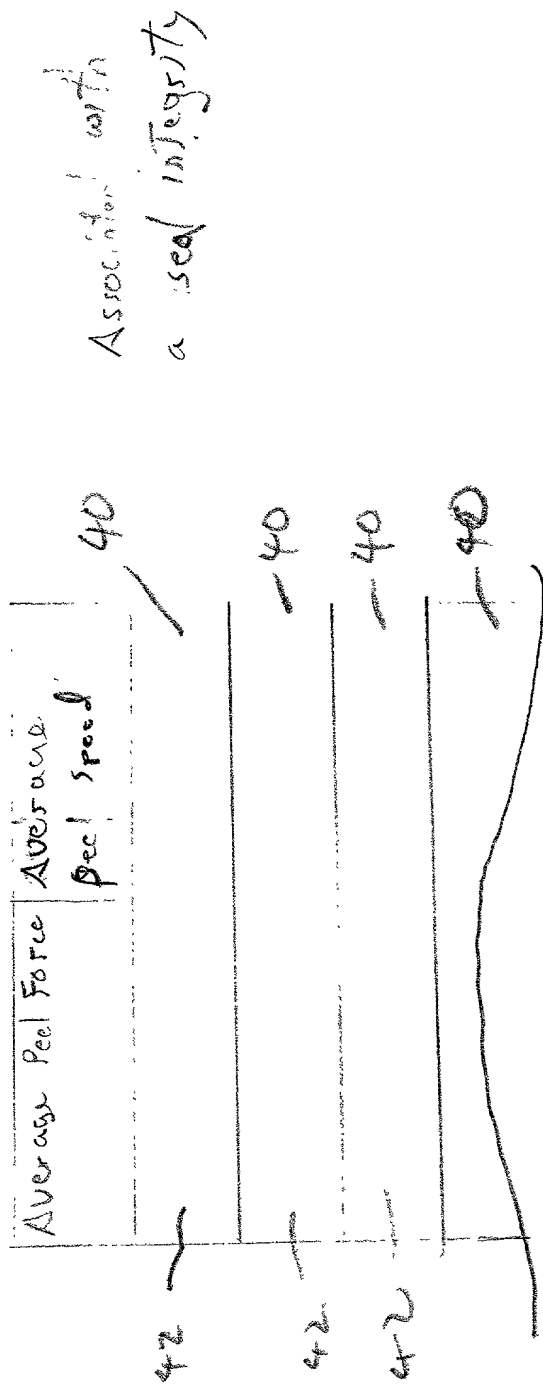


Figure 7A

009207" CHOCES60

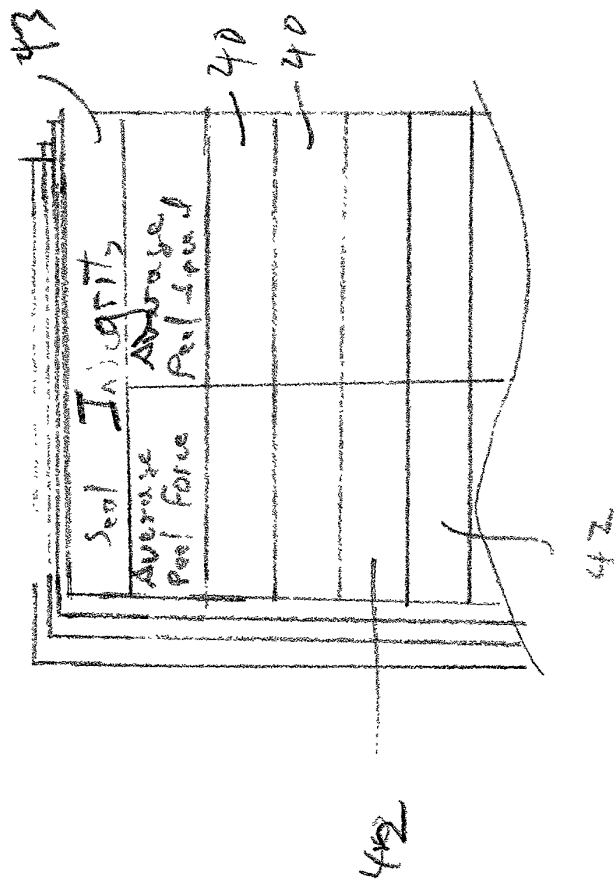
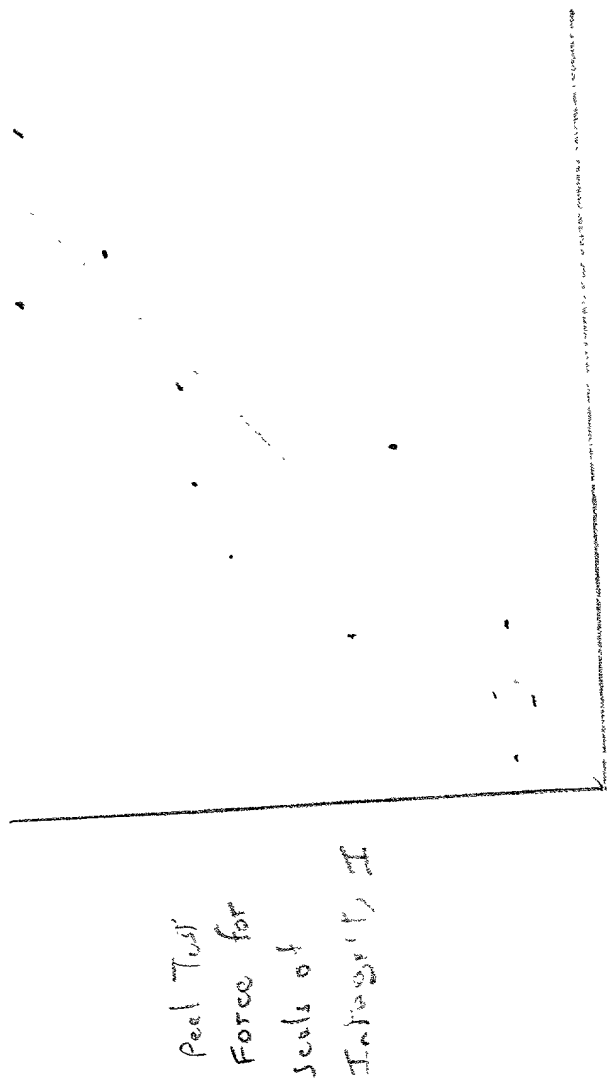


Figure 2B



Peel Speed for Seals of Integrity, I

Figure 8

00900T 2164650

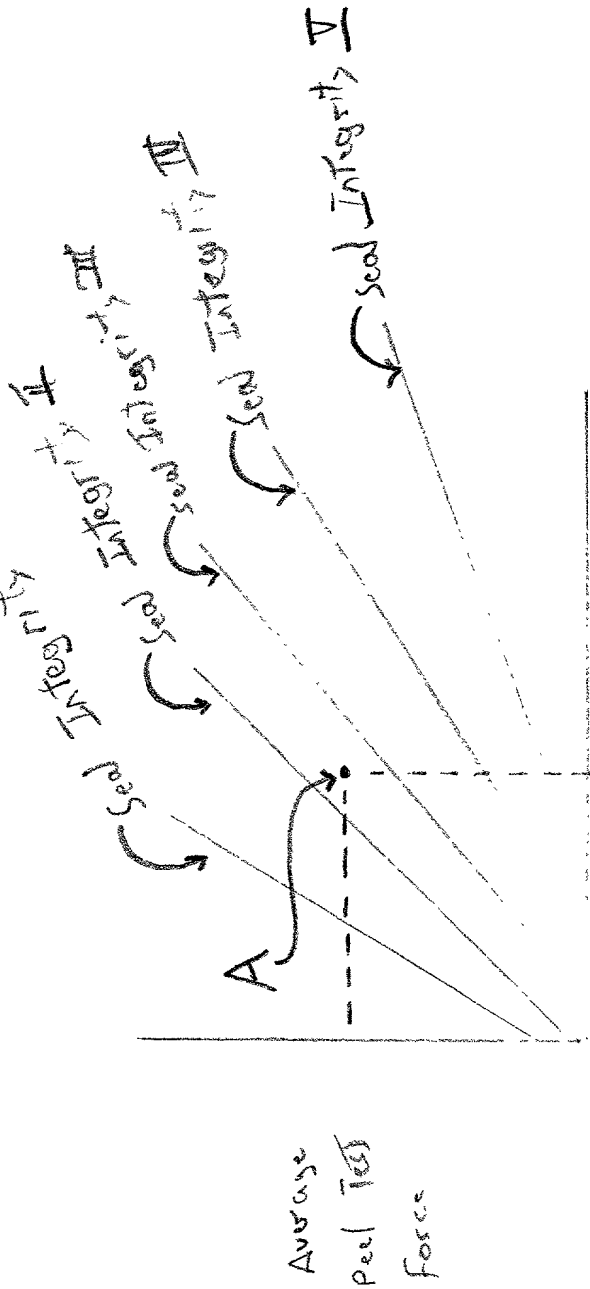


Figure 9

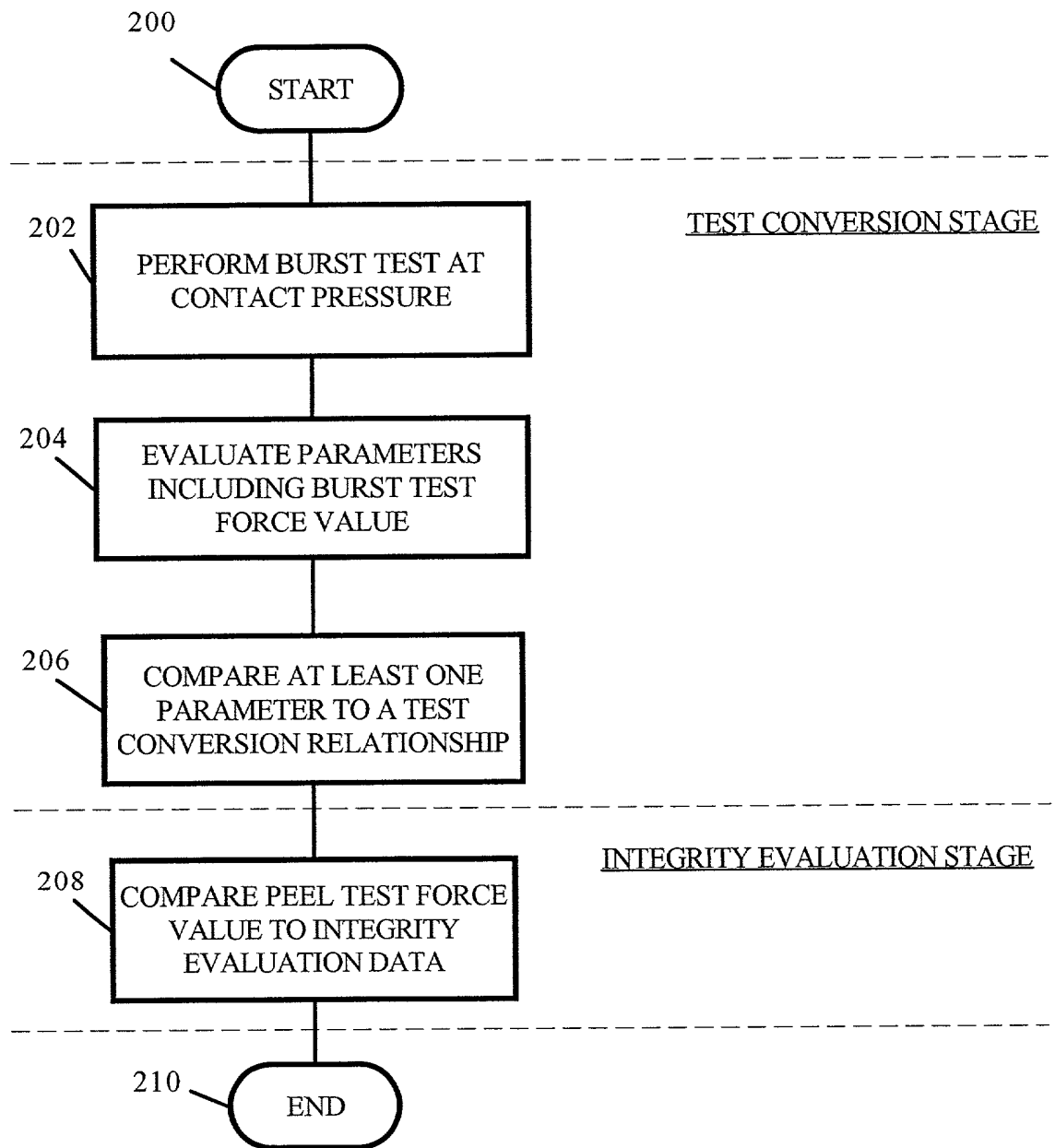


FIGURE 10

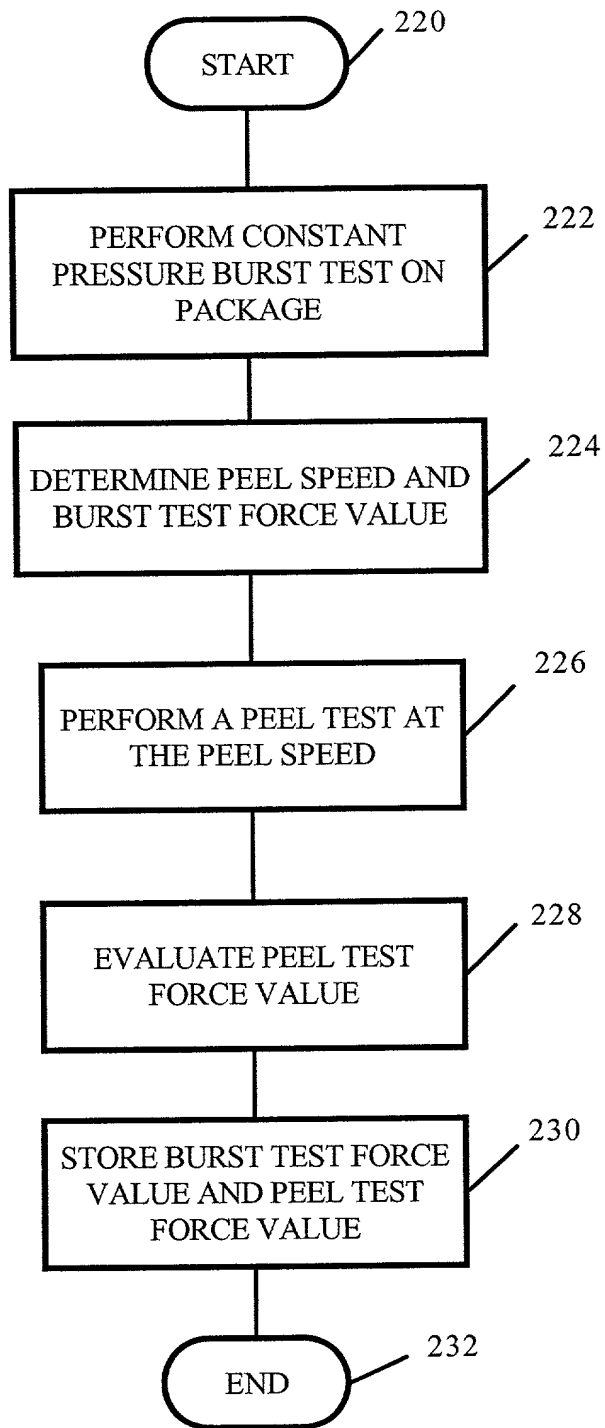


FIGURE 11

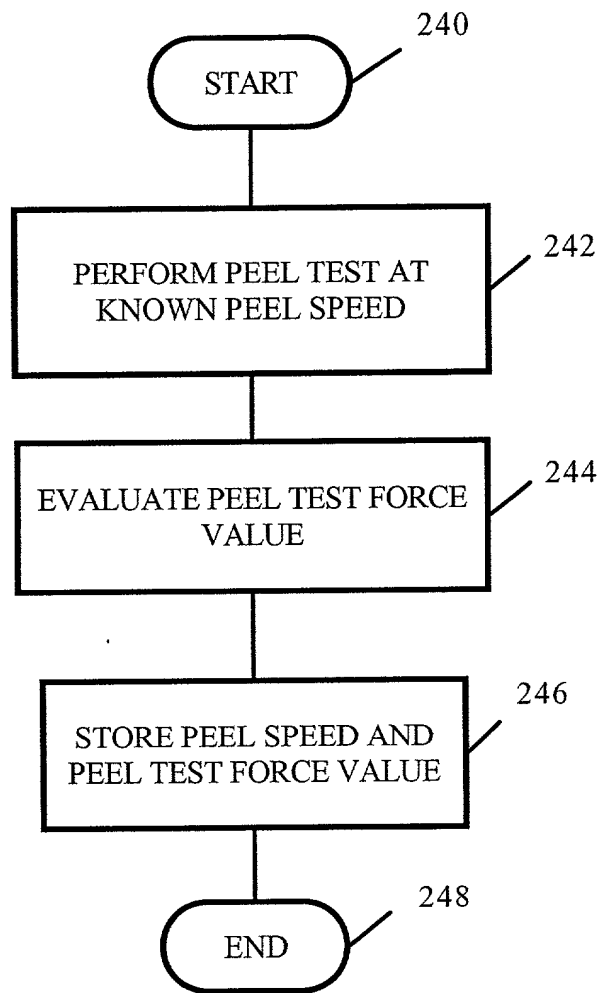


FIGURE 12

DECLARATION FOR PATENT APPLICATION

X Declaration Submitted With Initial Filing **OR** _____ Declaration Submitted After Initial Filing

As a below-named inventor, I hereby declare that:

My residence, post office address and citizenship is as stated below next to my name.

I believe that I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

EVALUATION OF BURST TEST RESULTS

the specification of which

X is attached hereto.

_____ was filed on _____, 2000 as U.S. Application Serial No. _____
and was amended on _____ if applicable (the "Application").

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability of the subject matter of the Application as defined in Title 37, Code of Federal Regulations ("C.F.R."), § 1.56.

I hereby claim foreign priority benefits under Title 35 United States Code § 119 (a)-(d) or § 365(b) of any foreign applications for patent or inventors certificate, or § 365(a) of any PCT international application which designated at least one country other than the United States of America listed below and have been identified below by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Numbers	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached	
				YES	NO

With respect to the Application, I hereby claim the benefit under 35 U.S.C. Section 119(e) of any United States provisional application(s) listed below:

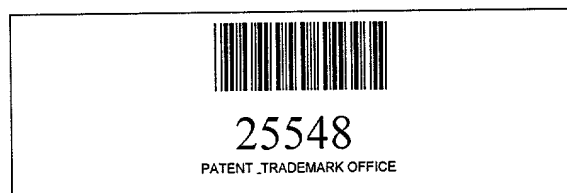
Application Number(s)	Filing Date (MM/DD/YYYY)

With respect to the Application, I hereby claim the benefit under 35 U.S.C. Section 120 of any United States application(s), or Section 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of the application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. Section 112, I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability of the subject matter of the Application as defined in Title 37, C.F.R., Section 1.56 which became available between the filing date of the prior application and the national or PCT International filing date of the Application:

U.S. Parent Application Number	PCT Parent Number	Parent Filing Date (MM/DD/YYYY)	Parent Patent Number (if applicable)

As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

Customer Number	25548
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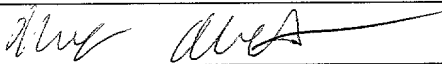
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Bar Code Label Above**

Please direct all correspondence to:

Terrance A. Meador
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401 B Street, Suite 1700
San Diego, CA 92101-4297

Phone: 619/699-2652 - Fax: 619/699-3452

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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Post Office Address	Same	
Citizenship	USA	

Full Name of Second Inventor (First, Middle, Family Name or Surname)		
Inventor Signature		Date:
Residence Address		
Post Office Address		
Citizenship		

Full Name of Third Inventor (First, Middle, Family Name or Surname)		
Inventor Signature		Date:
Residence Address		
Post Office Address		
Citizenship		